Teysuno®(tegafur, gimeracil and oteracil) capsules

Prescribing information: Please refer to the full Summary of Product Characteristics (SmPC) before prescribing, particularly in relation to dosage, precautions and side effects.

Name and active ingredients: Teysuno® 15 mg/4.35 mg/11.8 mg hard capsules containing 15 mg tegafur, 4.35 mg gimeracil and 11.8 mg oteracil (as monopotassium). Teysuno® 20 mg/5.8 mg/15.8 mg hard capsules containing 20 mg tegafur, 5.8 mg gimeracil and 15.8 mg oteracil (as monopotassium). **Indications (see SmPC for full indications):** as monotherapy or in combination with oxaliplatin or irinotecan, with or without bevacizumab, for the treatment of patients with metastatic colorectal cancer for whom it is not possible to continue treatment with another fluoropyrimidine due to hand-foot syndrome or cardiovascular toxicity that developed in the adjuvant or metastatic setting. **Dosage and administration (see SmPC for full details):** For metastatic colorectal cancer, the proposed dose for monotherapy is 30 mg/m2 b.i.d. days 1-14 with a one-week pause (± bevacizumab 7.5 mg/kg on day 1). For combination therapy (with oxaliplatin or irinotecan), 25 mg/m2 b.i.d. d1-14 followed by one-week pause is recommended. For details of Teysuno® doses and dose calculations see Teysuno® SmPC. Patients should be monitored closely and laboratory tests, including haematology, liver function, renal function, and serum electrolytes should be performed frequently. **Contraindications (see SmPC for full details):** Hypersensitivity to any of the active substances or to any of the excipients; history of severe and unexpected reactions to fluoropyrimidine therapy; known complete dihydropyrimidine dehydrogenase (DPD) deficiency; pregnancy and breastfeeding; severe bone marrow suppression; end stage renal disease patients requiring dialysis; co-administration of other fluoropyrimidines; recent or concomitant treatment with brivudine; contraindications for cisplatin, oxaliplatin, irinotecan and bevacizumab (refer to corresponding SmPCs). **Special warnings and precautions (see SmPC for full details):** Dose limiting toxicities include diarrhoea and dehydration. Most adverse reactions are reversible and can be managed by symptomatic therapy, dose interruptions and dose reductions. Patients with anorexia, asthenia, nausea, vomiting, diarrhoea, stomatitis, and gastrointestinal obstruction should be monitored closely for signs of dehydration. Treatment with Teysuno is not recommended in patients with severe renal impairment. Patients receiving oral coumarin-derivative anticoagulant therapy must have their INR or prothrombin time monitored closely and the anticoagulant dose adjusted accordingly. Warnings for: Hepatitis B reactivation, renal toxicity, ocular toxicity, hyperammonemia, DPD inducers, DPD deficiency, microsatellite instability (MSI), glucose/galactose intolerance/malabsorption, please refer to the full SmPC. Cannot be used as substitute for other 5-FU products. **Interactions (see SmPC for full details):** No interaction studies have been performed in adult or paediatric patients. Possible interactions with other fluoropyrimidines, CYP2A6 inhibitors, folinate/folinic acid, nitroimidazoles (including metronidazole and misonidazole), brivudine must not be administered concomitantly with Teysuno, methotrexate, clozapine, cimetidine, coumarin-derivative anticoagulant, phenytoin, allopurinol. **Driving and use of machinery:** Teysuno® has a moderate influence as fatigue, dizziness, blurred vision, and nausea are common adverse reactions. **Undesirable effects (see SmPC for full details):** Most commonly reported (≥1/10) adverse reactions are neutropenia, leukopenia, anaemia, thrombocytopenia, anorexia, peripheral neuropathy, diarrhoea, vomiting, nausea, constipation, fatigue, asthenia. *Common events* (≥1/100 to <1/10): febrile neutropenia, lymphopenia, dehydration, hypokalaemia, hyponatraemia, hypocalcaemia, hypomagnesaemia, hypoalbuminaemia, hyperkalaemia, insomnia, dizziness, headache, dysgeusia, vision disorder, lacrimal disorder, conjunctivitis, corneal disorder, hearing impairment, deafness, hypotension, deep vein thrombosis, hypertension, dyspnoea, epistaxis, hiccups, cough, gastrointestinal haemorrhage, stomatitis, gastrointestinal inflammation, flatulence, abdominal pain, dysphagia, abdominal discomfort, dyspepsia, dry mouth, hyperbilirubinaemia, alanine aminotransferase increased, aspartate aminotransferase increased, palmar-plantar erythrodysaesthesia syndrome, rash, skin hyperpigmentation, dry skin, pruritus, alopecia, musculoskeletal pain, renal failure, blood creatinine increased, glomerular filtration rate decreased, blood urea increased, mucosal inflammation, pyrexia, weight decreased, peripheral oedema, chills. For more information on infrequent or rare adverse reactions see the summary of product characteristics. Please refer to the full SmPC for complete information. **Legal Category:** POM. **Presentation and Basic NHS Price:** Teysuno® 15mg, 42 capsules, £111.89. Teysuno® 20 mg, 42 capsules, £149.04. **Marketing Authorisation (MA) Number:** Teysuno® 15mg, PL 40621/0037. Teysuno® 20 mg, PL 40621/0038. **MA holder:** Nordic Group B.V. Siriusdreef 41, 2132 WT Hoofddorp, The Netherlands**. Date of last revision of prescribing information:** 04/2026 **Item Code:** FPI-0058

Adverse events should be reported. Reporting forms and information can be found at yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Nordic Pharma at medinfo.uk@nordicpharma.com